

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN**

| | |
|--|--|
| <p>ELIZABETH BRUNSTAD, individually and as PERSONAL REPRESENTATIVE OF THE ESTATE OF JOHN BRUNSTAD, et al.,</p> <p style="text-align: center;">Plaintiffs,</p> <p>v.</p> <p>MEDTRONIC, INC., et al.,</p> <p style="text-align: center;">Defendants.</p> | <p>Court File No.: 3:14-cv-00255-slc</p> <p>RULE 26(f) JOINT REPORT</p> |
|--|--|

Pursuant to this Court’s Notice of Scheduling Conference and Fed. R. Civ. P. 26(f), counsel for Plaintiffs, Elizabeth Brunstad, individually and as Personal Representative of the Estate of John Brunstad, Rachel Brunstad, N.B., by and through his Guardian ad Litem Catherine Baier, R.B., by and through her Guardian ad Litem Catherine Baier, A.B., by and through her Guardian ad Litem Catherine Baier, and P.B., by through his Guardian ad Litem Catherine Baier (“Plaintiffs”), and for the Defendants Medtronic, Inc., Medtronic MiniMed, Unomedical Devices S.A. de C.V., and Unomedical A/S (“Defendants”), met and conferred via telephone and e-mail regarding a discovery and case schedule. Below is the resulting Joint Rule 26(f) Report.

PROPOSED DISCOVERY PLAN

A. Case Schedule

The parties propose the following respective case schedules:

| Event | Agreed Upon Deadlines | Disputed Deadlines |
|---|------------------------------|---------------------------|
| Rule 26 Disclosures | October 29, 2014 | |
| Deadline for adding new parties | November 28, 2014 | |
| Deadline for adding new insurers (non-insurers) | November 28, 2014 | |

| | | |
|---|--------------------|--|
| Deadline for amendments to pleadings (without leave) | November 28, 2014 | |
| Disclosure of liability expert reports by Plaintiffs and Defendants | | <u>Plaintiffs' Proposed Date:</u> May 31, 2015 (simultaneous) <u>Medtronic and Unomedical's Proposed Dates:</u> Disclosure by Plaintiffs: May 29, 2015 Disclosure by Defendants: Jun 19, 2015 |
| Disclosure of rebuttal expert reports by Plaintiffs and Defendants | | <u>Plaintiffs Proposed Date:</u> June 30, 2015 (simultaneous) <u>Medtronic and Unomedical's Proposed Dates:</u> Disclosure by Plaintiffs: July 10, 2015 Disclosure by Defendants: July 31, 2015 |
| Dispositive motions deadline | | <u>Plaintiffs and Medtronic's Proposed Date:</u> June 29, 2015 <u>Unomedical's Proposed Date:</u> August 21, 2015 |
| Disclosure of Plaintiffs' Damage Expert Reports | June 30, 2015 | |
| Disclosure of Defendants' Rebuttal Damage Expert Reports | July 31, 2015 | |
| Settlement letters | September 11, 2015 | |
| Discovery cut-off | September 30, 2015 | |
| Rule 26(a)(3) disclosures and all motions in limine | October 23, 2015 | |
| Final pretrial conference | November 9, 2015 | |
| Trial | January 4, 2016 | |

B. Modifications to Limitations on Discovery Imposed by the Federal Rules.

The parties do not request changes to the limitations imposed by the Federal Rules of Civil Procedure with one exception. For depositions taken pursuant to Fed. R. Civ. P. 30, the parties believe that fifteen depositions per party will likely be sufficient but, given the complexity of this matter, anticipate there may develop a need to seek the Court's further guidance at a later date.

OTHER INFORMATION REQUESTED IN STANDING ORDER

1. A concise statement of the nature of the case.

Plaintiff: This is a product liability action arising out of Decedent John Brunstad's use of three products: a Medtronic MiniMed Paradigm Revel™ Model MMT-523 Insulin Pump (Serial No. PAR762109H), a MiniMed Paradigm MMT-382EA Silhouette® Infusion Set, and a MiniMed Paradigm MMT-326A Reservoir.

During the early hours of April 6, 2011, John Brunstad died as a result of a hypoglycemic event when Mr. Brunstad's pump malfunctioned, causing all the insulin in his reservoir to be injected into him at once. Subsequent to Mr. Brunstad's death, Mrs. Brunstad received recall letters pertaining to the pump and the infusion sets used by Mr. Brunstad prior to his death. Each of these recall letters specified that the defects prompting the recalls could result in either too little or too much insulin being dispensed to a pump user. Medtronic has taken possession of the pump, and Plaintiffs have not had an opportunity to inspect it at this time.

Plaintiffs contend that Medtronic and Unomedical, who designed, manufactured, and/or distributed the three devices at issue, were negligent in the design, warning, and manufacture of these devices, and contend that they knew or should have known well in advance of Mr. Brunstad's death that such an event was likely to occur.

Defendants have asserted a number of defenses in their Answers, including the following: (1) failure to state a claim, (2) federal preemption, (3) the learned intermediary doctrine, (4) contributory negligence, (5) assumption of risk, and (6) provisions of the Wisconsin Uniform Commercial Code.

Defendants: This product liability matter involves claims against Medtronic Inc., Medtronic MiniMed Inc., Unomedical Devices S.A. de C.V., and Unomedical A/S (collectively “Defendants”) relating to several prescription medical devices, a MiniMed Paradigm Revel™ Model MMT-523 Insulin Pump (Serial No. PAR762109H), the MiniMed Paradigm MMT-382EA Silhouette® Infusion Set, and the MiniMed Paradigm MMT-326A Reservoir that the decedent, John Brunstad, was allegedly using on or about April 6, 2011, to treat his diabetes.

Plaintiffs contend that due to an alleged, unidentified defect in one or more of these medical devices being used by Mr. Brunstad on April 6, 2011, he experienced a hypoglycemic event that caused his death. Plaintiffs allege that the unidentified malfunction or defect in the medical devices contributed to an over-delivery of insulin, which ultimately caused Mr. Brunstad’s death. After Mr. Brunstad’s death, the Medical Examiner asked Medtronic to test the Insulin Pump. The Insulin Pump passed all functional testing.

Defendants deny that they were negligent in any respect as alleged by Plaintiffs, deny that they breached any warranty as alleged by Plaintiffs, and deny any malicious acts or intentional disregard of Mr. Brunstad’s rights and safety. Defendants further deny that they are liable to Plaintiffs in any manner whatsoever, and deny that Plaintiffs are entitled to any of the relief requested in the Complaint.

Moreover, the evidence to date suggests that the injuries alleged in the Complaint may have been caused, in whole or in part, (1) by pre-existing medical conditions of Mr. Brunstad unrelated to the allegations in the Complaint; and (2) by operation of nature or as a result of circumstances over which Defendants had, and continue to have, no control.

Finally, in addition to defending on the merits, Defendants have asserted a number of defenses in their Answers, including the following: (1) Plaintiffs fail to state a cause of action, (2) Plaintiffs claims are preempted, in whole or in part, by federal law, including the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321-394 and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), (3) the learned intermediary doctrine, (4) contributory negligence, (5) assumption of risk, and (6) applicable provisions of the Wisconsin Uniform Commercial Code.

2. The names of any related cases.

Plaintiff: Plaintiff is not aware of any related cases in this jurisdiction.

Defendants: There are no related cases.

3. A specific statement of the material factual and legal issues to be resolved at trial.

Plaintiff:

Key Legal Issues:

- i. Plaintiffs anticipate preemption is an issue that will be disposed of prior to trial. It does not apply here since the claims are all either parallel claims (premised on conduct that violated the PMA while also violating common law standards) or involve the infusion sets were are Class II medical devices.
- ii. Choice of law questions as to whether Wisconsin or California substantive law governs.
- iii. Whether Plaintiffs are entitled to punitive damages.

Key Factual Issues:

- i. The reason behind Defendants' recalls of the devices.

- ii. When Defendants knew of the defects causing the insulin canister to fully empty into patients.
- iii. The hazard analysis, testing and monitoring of the devices performed by Defendants.
- iv. The monitoring and reporting of these adverse events to Plaintiff's doctors and the Plaintiff.
- v. Adherence to manufacturing requirements.
- vi. The amount of Plaintiffs' damages.

Defendants:

Key Legal Issues:

- i. Whether Plaintiffs' claims are preempted by federal law (Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321-394 and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008));
- ii. Whether there is any evidence that the medical devices contained a manufacturing and/or design defect as defined by applicable law;
- iii. Whether contributory negligence bars Plaintiffs' recovery; and
- iv. Whether punitive damages are allowed under Plaintiffs' claims.

Key Factual Issues:

- i. Decedent's use of the insulin pump, infusion set, and reservoir allegedly worn by him at the time of his death;
- ii. Decedent's full medical history, including but not limited to the course of his diabetes, his other medical conditions, and the circumstances surrounding Decedent's death; and
- iii. Any damages alleged in the Complaint.

The parties further state that the course of the litigation may require discovery concerning other matters or issues beyond those specifically identified herein.

4. A description of any amendments to the pleadings that any party intends to make.

Plaintiff: Plaintiffs are not aware of any amendments that need to be made at this time.

Defendants: Defendants do not intend to seek amendment of the pleadings.

- 5. The identity of any new parties to be added, including an explanation as to why these parties must (or should) be added.**

Plaintiff: Plaintiffs are not aware of any parties that need to be added at present.

Defendants: Defendants are not aware of any parties that need to be added.

- 6. The estimated trial length.**

The parties estimate the need for 15 trial days.

- 7. Any other matter affecting the just, speedy and inexpensive disposition of this case, or which the court should take into account in setting the schedule.**

Plaintiff: None known at this time.

Defendants: None known at this time.

Dated: October 10, 2014

GOLDENBERG LAW, PLLC

By: /s/ Stuart L. Goldenberg
Stuart Goldenberg
Marlene J. Goldenberg
800 LaSalle Avenue, Suite 2150
Minneapolis, MN 55402
Telephone: 612-333-4662

and

Khaldoun A. Baghdadi (CA #190111)
Sara M. Peters (CA #260610)
Walkup, Medodia, Kelly & Schoenberger
650 California Street, 26th floor
San Francisco, CA 94108-2615
Telephone: 415-981-7210

and

Markus Yira (WI #1040326)
102 Main Street South, Suite 201
P.O. Box 518
Hutchinson, MN 55350

ATTORNEYS FOR PLAINTIFFS

Dated: October 10, 2014

MASLON EDELMAN BORMAN & BRAND, LLP

By: /s/ Emily M. Rome

David T. Schultz (WI Bar No. 1036046)

Emily M. Rome (MN Bar No. 0296648)

Nicole E. Narotzky (MN Bar No. 0329885)

3300 Wells Fargo Center

90 South Seventh Street

Minneapolis, MN 55402

Telephone: 612-672-8200

Facsimile: 612-672-8397

E-mail: david.schultz@maslon.com

emily.rome@maslon.com

nicole.narotzky@maslon.com

ATTORNEYS FOR DEFENDANTS

MEDTRONIC, INC. and

MEDTRONIC MINIMED, INC.

Dated: October 10, 2014

JOHNSON & LINDBERG, P.A.

By: /s/ Michael C. Lindberg
Michael C. Lindberg
3800 American Boulevard West, Suite 780
Minneapolis, MN 55431
Telephone: 952-956-6200
mlindberg@johnsonlindberg.com

THOMPSON HINE LLP

By: /s/ Z. Ileana Martinez
Z. Ileana Martinez
Two Alliance Center
3560 Lenox Road, Suite 1600
Atlanta, GA 30326
Telephone: 404-541-2964
Facsimile: 404-541-2905
Email: ileana.martinez@thompsonhine.com

**ATTORNEYS FOR DEFENDANT
UNOMEDICAL A/S**

1068547